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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/750,986	12/28/2000	Alexander Steinbuchi	Bayer 9998.2-HCL	1415

7590 05/04/2004

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EXAMINER

RAMIREZ, DELIA M

ART UNIT PAPER NUMBER

1652

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/750,986		STEINBUCHER ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Delia M. Ramirez		1652	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-13 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

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## **DETAILED ACTION**

### ***Status of the Application***

Claims 1-13 are pending.

Applicant's submission of a preliminary amendment of claim 3 and the specification in a communication filed on 12/28/2000 is acknowledged.

It is noted that claims 7-8 are directed to non-statutory subject matter, i.e. a use, and not to a method or a product. For restriction purposes, it will be assumed that claims drawn to a use are instead drawn to a method of use.

### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-2, drawn in part to a eugenol hydroxylase, classified in class 435, subclass 189.
  - II. Claims 1-2, drawn in part to coniferyl alcohol dehydrogenase, classified in class 435, subclass 190.
  - III. Claims 1-2, drawn in part to coniferylaldehyde dehydrogenase, classified in class 435, subclass 191.
  - IV. Claims 1-2, drawn in part to ferulic acid deacylase, classified in class 435, subclass 227.
  - V. Claims 1-2, drawn in part to vanillin dehydrogenase, classified in class 435, subclass 191.
  - VI. Claims 3-7, drawn in part to a polynucleotide encoding a eugenol hydroxylase, vectors and microorganisms comprising said polynucleotide, as well as a method of transformation of said microorganisms with said vectors, classified in class 536, subclass 23.2.
  - VII. Claims 3-7, drawn in part to a polynucleotide encoding a coniferyl alcohol dehydrogenase, vectors and microorganisms comprising said polynucleotide, as well as a

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method of transformation of said microorganisms with said vectors, classified in class 536, subclass 23.2.

- VIII. Claims 3-7, drawn in part to a polynucleotide encoding a coniferylaldehyde dehydrogenase, vectors and microorganisms comprising said polynucleotide, as well as a method of transformation of said microorganisms with said vectors, classified in class 536, subclass 23.2.
- IX. Claims 3-7, drawn in part to a polynucleotide encoding a ferulic acid deacylase, vectors and microorganisms comprising said polynucleotide, as well as a method of transformation of said microorganisms with said vectors, classified in class 536, subclass 23.2.
- X. Claims 3-7, drawn in part to a polynucleotide encoding a vanillin dehydrogenase, vectors and microorganisms comprising said polynucleotide, as well as a method of transformation of said microorganisms with said vectors, classified in class 536, subclass 23.2.
- XI. Claim 8, drawn in part to a method of making coniferyl alcohol using a microorganism transformed with a nucleic acid encoding a eugenol hydroxylase, classified in class 435, subclass 155.
- XII. Claim 8, drawn in part to a method of making coniferylaldehyde using a microorganism transformed with a nucleic acid encoding a coniferyl alcohol dehydrogenase, classified in class 435, subclass 147.
- XIII. Claim 8, drawn in part to a method of making ferulic acid using a microorganism transformed with a nucleic acid encoding a coniferylaldehyde dehydrogenase, classified in class 435, subclass 136.

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- XIV. Claim 8, drawn in part to a method of making vanillin using a ferulic acid deacylase with a microorganism transformed with a nucleic acid encoding a ferulic acid deacylase, classified in class 435, subclass 156.
- XV. Claim 8, drawn in part to a method of making vanillic acid using a microorganism transformed with a nucleic acid encoding a vanillin dehydrogenase, classified in class 435, subclass 136.
- XVI. Claim 9, drawn to a method of making coniferyl alcohol using a eugenol hydroxylase, classified in class 435, subclass 25.
- XVII. Claim 10, drawn to a method of making coniferylaldehyde using a coniferyl alcohol dehydrogenase, classified in class 435, subclass 26.
- XVIII. Claim 11, drawn to a method of making ferulic acid using a coniferylaldehyde dehydrogenase, classified in class 435, subclass 26.
- XIX. Claim 12, drawn to a method of making vanillin using a ferulic acid deacylase, classified in class 435, subclass 18.
- XX. Claim 13, drawn to a method of making vanillic acid using a vanillin dehydrogenase, classified in class 435, subclass 26.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions VI-X and XI-XV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the DNA of Inventions VI-X can be used to make the proteins of Inventions I-V as well as in the methods of Inventions XI-XV, respectively.

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3. Inventions I-V and XVI-XX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the proteins of Inventions I-V can be used to elicit antibodies as well as in the methods of Inventions XVI-XX, respectively.

4. Inventions I-V and XI-XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the proteins of Inventions I-V are neither used nor made by the methods of Inventions XI-XV.

5. Inventions VI-X and XVI-XX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the DNAs of Inventions VI-X are neither used nor made by the methods of Inventions XVI-XX.

6. Groups I-X each comprise a chemically unrelated structure capable of separate manufacture, use, and effect. The DNA in Groups VI-X comprises a nucleic acid sequence whereas the proteins of Groups I-V each comprise an unrelated amino acid sequence. The DNAs of Groups VI-X have other uses besides encoding the proteins of Group I-V, such as a hybridization probe or in gene therapy. The proteins of Groups I-V can be used to elicit antibodies. Further, the proteins of Groups I-V can be prepared by processes which are materially different from recombinant expression of the DNAs of Groups VI-X, such as by chemical synthesis, or by isolation and purification from natural sources.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, as shown by their different classification, restriction for examination purposes as indicated is proper.

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8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

9. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

10. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement can be traversed (37 CFR 1.143).

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11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

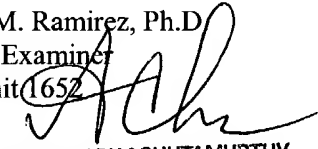
12. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 872-9306. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

DR  
April 29, 2004

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Art Unit 1652  
  
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